

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently amended) A propellant-free pharmaceutical preparation composition comprising:

- (a) an active substance comprising tiotropium or a pharmaceutically acceptable salt thereof, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH ~~between 2.0 and 3.0~~ of from 2.5 to 3.0;
- (d) a pharmacologically acceptable preservative; and
- (e) a complexing agent comprising edetic acid or an edetic acid salt in an amount ~~of~~ from greater than 0 ~~and up to~~ 25 mg/100 mL,

optionally including a stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives but containing no propellant; and wherein the amount of edetic acid or an edetic acid salt results in a reduction in the incidence of spray anomalies.

2. (Currently amended) The pharmaceutical preparation composition according to claim 1, wherein the tiotropium salt is selected from the group consisting of salts with a bromide, chloride, iodide, monomethylsulphate, methanesulphonate and/or p-toluenesulphonate anion.

3. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the active substance is tiotropium bromide.

4. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the active substance is tiotropium bromide monohydrate.

5. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the solvent is water.

6. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 2, wherein the solvent is water.

7. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 3, wherein the solvent is water.

8. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 4, wherein the solvent is water.

9. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

10. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 2, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

11. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 3, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

12. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 4, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

13. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 9, wherein the solvent is a water-ethanol mixture with up to 60 vol.% of ethanol.

14. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 13, wherein the solvent is a water-ethanol mixture with up to 30 vol.% of ethanol.

15. (Cancelled)

16. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the pharmaceutical ~~preparation~~ composition does not contain a stabilizer.

17. (Cancelled)

18. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the edetic acid salt is present in an amount of from 5 to ~~less than~~ 10 mg/100 ml.

19. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the edetic acid salt is sodium edetate.

20. – 21. (Cancelled)

22. (Currently amended) The pharmaceutical ~~preparation~~ composition according to ~~claim 20~~ claim 1, wherein the pH is ~~between 2.7 and 3.0~~ from 2.7 to 3.0.

23. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claims 1, wherein the concentration based on tiotropium is between 0.001% and 3% by weight.

24. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 23, wherein the concentration based on tiotropium is between 0.0005% to 0.5% by weight.

25. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 24, wherein the concentration based on tiotropium is between 0.0005% to 0.25% by weight.

26. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 25, wherein the concentration based on tiotropium is between 0.001% to 0.1% by weight.

27. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 1, wherein the pharmacologically acceptable preservative is benzalkonium chloride.

28. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claims 1, wherein the pharmaceutical ~~preparation~~ composition comprises a pharmacologically acceptable adjuvant or additive.

29. (Currently amended) The pharmaceutical ~~preparation~~ composition

according to claim 28, wherein pharmacologically acceptable adjuvant or additive is an antioxidant.

30. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claims 1, wherein the pharmaceutical ~~preparation~~ composition contains no cosolvents and/or pharmacologically acceptable adjuvants and additives apart from the preservative.

31. (Currently amended) A pharmaceutical ~~preparation~~ composition comprising water, 0.1% by weight of tiotropium bromide, 0.01% by weight of benzalkonium chloride, and 0.05% by weight of sodium edetate, which is adjusted to a pH of 3.0 using hydrochloric acid.

32. – 37. (Cancelled)

38. (Currently amended) A method for administering a pharmaceutical ~~preparation~~ composition according to claim 1, comprising nebulizing the pharmaceutical ~~preparation~~ composition in an inhaler selected from the group consisting of: (a) an inhaler according to the Weston Nebulizer, or (b) an inhaler according to the Jaeger Nebulizer B.

39. (Currently amended) A method for administering a pharmaceutical ~~preparation~~ composition according to claim 1, comprising nebulizing the pharmaceutical ~~preparation~~ composition in an inhaler which nebulizes defined amounts of the pharmaceutical ~~preparation~~ composition by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.

40. (Original) The method according to claim 39, wherein at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction

of the nozzle opening at an angle of from 20 degrees to 160 degrees.

41. (Currently amended) The method according to claim 39, wherein the defined amounts of the pharmaceutical ~~preparation~~ composition are 10 to 50 microliters.

42. (Original) The method according to claim 38, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

43. (Original) The method according to claim 39, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

44. (Currently amended) The method according to claim 38, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

45. (Currently amended) The method according to claim 39, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

46. (Currently amended) The method according to claim 38, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

47. (Currently amended) The method according to claim 39, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

48. (Currently amended) The method according to claim 38, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 98% of all actuations of the

inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

49. (Currently amended) The method according to claim 39, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

50. (Currently amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition according to claim 1.

51. (Currently amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition using the method of claim 38.

52. (Currently amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition using the method of claim 39.

53. (Currently amended) A propellant-free pharmaceutical ~~preparation~~ composition comprising:

- (a) an active ingredient consisting essentially of a tiotropium salt, in a concentration based on tiotropium of between 0.0005 and 5% by weight;
- (b) a solvent selected from water or a water/ethanol mixture;
- (c) acid for achieving a pH ~~between 2.0 and 3.0~~ of from 2.5 to 3.0;
- (d) a pharmacologically acceptable preservative; and

(e) a complexing agent comprising edetic acid or an edetic acid salt in an amount of from greater than 0 ~~and up to~~ 25 mg/100 mL,

optionally including a stabilizer, a pharmacologically acceptable cosolvent, or other pharmacologically acceptable adjuvants and additives but containing no propellant; and wherein the amount of edetic acid or an edetic acid salt results in a reduction in the incidence of spray anomalies.

54. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the tiotropium salt is selected from the group consisting salts with a bromide, chloride, iodide, monomethylsulphate, methanesulphonate and/or p-toluenesulphonate anion.

55. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the tiotropium salt is tiotropium bromide.

56. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the tiotropium salt is tiotropium bromide monohydrate.

57. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the solvent is water.

58. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 54, wherein the solvent is water.

59. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 55, wherein the solvent is water.

60. (Currently amended) The pharmaceutical preparation composition according to claim 56, wherein the solvent is water.

61. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

62. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 54, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

63. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 55, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

64. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 56, wherein the solvent is a water-ethanol mixture with up to 70 vol.% of ethanol.

65. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 61, wherein the solvent is a water-ethanol mixture with up to 60 vol.% of ethanol.

66. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 65, wherein the solvent is a water-ethanol mixture with up to 30 vol.% of ethanol.

67. (Cancelled)

68. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the pharmaceutical ~~preparation~~ composition does not contain a stabilizer.

69. (Cancelled)

70. (Currently amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the edetic acid salt is sodium edetate.

71. (Cancelled)

72. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to ~~claim 71~~ claim 53, wherein the pH is ~~between 2.7 and 3.0~~ from 2.7 to 3.0.

73. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the concentration based on tiotropium is between 0.001% and 3% by weight.

74. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 73, wherein the concentration based on tiotropium is between 0.0005% to 0.5% by weight.

75. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 74, wherein the concentration based on tiotropium is between 0.0005% to 0.25% by weight.

76. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 75, wherein the concentration based on tiotropium is between 0.001% to 0.1% by weight.

77. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the pharmacologically acceptable preservative is benzalkonium chloride.

78. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the pharmaceutical ~~preparation~~ composition comprises a pharmacologically acceptable adjuvant or additive.

79. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 78, wherein pharmacologically acceptable adjuvant or additive is an antioxidant.

80. (Currently Amended) The pharmaceutical ~~preparation~~ composition according to claim 53, wherein the pharmaceutical ~~preparation~~ composition contains no cosolvents and/or pharmacologically acceptable adjuvants and additives apart from the preservative.

81. (Currently Amended) A method for administering a pharmaceutical ~~preparation~~ composition according to claim 53, comprising nebulizing the pharmaceutical ~~preparation~~ composition in an inhaler selected from the group consisting of: (a) an inhaler according to the Weston Nebulizer, or (b) an inhaler according to the Jaeger Nebulizer B.

82. (Currently Amended) A method for administering a pharmaceutical ~~preparation~~ composition according to claim 53, comprising nebulizing the pharmaceutical ~~preparation~~ composition in an inhaler which nebulizes defined amounts of the pharmaceutical ~~preparation~~ composition by the application of pressures from 100 to 600 bar through a nozzle having at least one nozzle opening with a depth of 2 to 10 microns and a width of 5 to 15 microns to form an inhalable aerosol.

83. (Previously presented) The method according to claim 82, wherein at least one nozzle opening is at least two nozzle openings which are inclined relative to one another in the direction of the nozzle opening at an angle of from 20 degrees to 160 degrees.

84. (Currently Amended) The method according to claim 82, wherein the defined amounts of the pharmaceutical ~~preparation~~ composition are 10 to 50 microliters.

85. (Previously presented) The method according to claim 81, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

86. (Previously presented) The method according to claim 82, wherein the inhaler is 9 cm to 15 cm long and 2 cm to 4 cm wide.

87. (Currently Amended) The method according to claim 81, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

88. (Currently Amended) The method according to claim 82, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 25%.

89. (Currently Amended) The method according to claim 81, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

90. (Currently Amended) The method according to claim 82, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 97% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

91. (Currently Amended) The method according to claim 81, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

92. (Currently Amended) The method according to claim 82, wherein the mass of pharmaceutical ~~formulation~~ composition delivered in at least 98% of all actuations of the inhaler is between 5 mg and 30 mg within a range of tolerance of 20%.

93. (Currently Amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition according to claim 53.

94. (Currently Amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition using the method of claim 81.

95. (Currently Amended) A method of treating asthma or COPD in a patient, the method comprising administering to the patient a pharmaceutical ~~preparation~~ composition using the method of claim 82.